REMARKS

The Office Action reportedly mailed June 18, 2003 (and faxed to the undersigned on August 22, 2003) has been received and reviewed. All claims stand rejected. Reconsideration is respectfully requested.

A. Parallel Litigation:

In view of parallel litigation in the United Kingdom with respect to the corresponding European Patent Office patent, applicants are electing to cancel the non-process claims without prejudice or disclaimer. Applicants intend to prosecute a related application with the claims canceled herein after more information has developed from the United Kingdom litigation.

The United Kingdom litigation does not challenge the process claims generally corresponding to claims 4 through 6 herein, so applicants are proceeding with those claims in the instant application. If more information regarding the litigation is desired by the Office, it is kindly requested to contact the undersigned who will promptly provide the requested information.

B. Claim Objections:

Claims 17 and 18 were objected to as assertedly failing to further limit claim 14 from which they depend. Although applicants do not agree with the objection, these claims have been canceled without prejudice or disclaimer, thus mooting the objection.

C. 35 U.S.C. § 102:

Claims 1-3, 7 and 9 were rejected as assertedly being anticipated by Sas et al. Although applicants do not agree with the rejection, these claims have been canceled without prejudice or disclaimer, thus mooting the rejection.

D. 35 U.S.C. § 103:

Claims 4-6 are rejected under 35 U.S.C. § 103 in view of Sas et al. and van Vliet et al. Applicants traverse the rejection.

Applicants have amended process claims 4-6 to clarify that, after filtration and washing, crystals of the compound are allowed to age in the presence of water for a period of time of at least 24 hours before drying the crystals. (*See*, amended claims 4-6). Support for the amendment can be found in the as-filed Specification at page 3, lines 16-17 and 32-34. It is respectfully

submitted that no new matter has been added.

The Office Action relies on Examples 1-4 of Sas et al. for teaching a process in which crystals of the compound (seed crystals) are "aged" in the presence of water for one hour (*i.e.*, Example 2) and argues that it would have been obvious to a person of ordinary skill in the art at the time the invention was made to optimize the time period for "aging" crystals to at least 24 hours or 3-6 days.

However, Sas et al., particularly in Example 2, teaches a time period of one hour for allowing the crystals to form or to grow before the crystals are filtered off, washed, and dried. Sas at al. teaches nothing with respect to treating tibolone crystals after filtration and washing, but before drying. Hence, the treatment of wet crystals of tibolone as set forth in amended claim 4 is neither taught nor suggested by Sas et al.

The Examiner is correct that the time period mentioned in Sea et al., *i.e.*, the time needed to grow crystals of tibolone, could be optimized by one skilled in the art. However, Sas et al. is completely silent about doing anything with the wet crystals after filtration and washing but before drying the crystals.

Similarly, Van Vliet at al. describes on page 115, left column, last paragraph, that "the precipitate [*i.e.*, the crystals of tibolone] was collected, washed with water and dried", but does not teach or suggest any treatment of wet crystals of tibolone after filtration and washing but before drying of the crystals.

In view of the comment on page 6, last paragraph, of the Office Action, *i.e.*, "because the optimization of the time period for aging crystals [for a] longer period of time in order to obtain more desirable crystals e.g., highly pure or desired polymorphous forms, is considered well within the skill of artisan", the Office should also acknowledge that a difference exists between the "aging" taught by the prior art references including Roberts et al. (*i.e.*, in order to obtain more crystals or to grow crystals) and the aging of wet crystals in accordance with the present invention (*i.e.*, in order to improve the purity and stability of tibolone crystals after drying). (*See*, page 3, lines 9-11 of the Specification).

As a result of aging in accordance with the invention, crystals of tibolone are obtained with a higher purity and with a better stability as illustrated by comparing the results of

(comparative) Example 1 with Example 2 in the specification. Nothing in the art would suggest this unexpected result (or applicants' claimed process), and applicants accordingly request that the rejection be withdrawn.

If it would be considered helpful to the Office, applicants are willing to schedule an interview with the examiner, her supervisor, the undersigned, and an organic chemist with a Ph.D. degree in order to explain the invention, and hopefully facilitate the prosecution of the instant application.

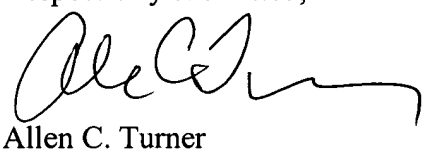
E. 35 U.S.C. § 103:

Claims 10, 11, and 13-20 were rejected as being unpatentable under 35 U.S.C. § 103 in view of Sas et al., van Vliet et al. and de Haan. Although applicants do not agree, these claims have been canceled without prejudice or disclaimer, thus mooting the rejection.

Conclusion

In view of the foregoing, the application should be in condition for allowance. If questions should remain after consideration of the foregoing, however, the Office is kindly requested to contact applicants' attorney at the address or telephone number given herein.

Respectfully submitted,



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Date: November 7, 2003